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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,088	04/01/2005	Chung K. Chu	G25-080US Nat	7531

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/530,088	CHU ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/1/05, 10/16/06, 10/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/US03/39029, filed December 8, 2003, which claims benefit of provisional application 60/431812, filed December 9, 2002. Claims 1-40 and 45-47 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted April 1, 2005 is acknowledged wherein claims 5-9 and 17-19 are amended, claims 41-44 are cancelled, new claims 45-47 are introduced, and the specification is amended to include a statement of government rights in the invention.

Claim Objections

Claim 47 is objected to for depending from a cancelled base claim, in this case claim 41. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 47 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 47 provides for use according to claim 41, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8-12, 19-22, 30, and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Liotta et al. (US patent 5852027, cited in PTO-1449) Liotta et al. discloses methods for prevention and treatment of viral infections, including HIV infections, comprising administering an antiviral 1,3-dioxolane nucleoside, and pharmaceutical compositions comprising such nucleosides. (column 13, line 33 – column 14, line 33) specific pharmaceutically acceptable compounds of the invention of Liotta et al. include compounds identical to those of instant claim 1, including wherein

R1 is hydrogen, alkyl, or acyl. Additionally, 2'-deoxy-3'-oxothymidine (R1=H) is shown to inhibit HIV activity *in vitro*. (figure 2, compound 11, also shown TBDMS-protected as compound 6, column 17, lines 33-45) Thus the instant claims are anticipated by Liotta et al.

Claims 1, 5-12, 17-30, and 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Belleau et al. (US patent 7199202, cited in PTO-1449) Belleau et al. discloses a variety of compounds including cis- and trans- 2-acetoxymethyl-4-(thymin-1'-yl) 1,3-dioxolane, and cis- and trans- 2-hydroxymethyl-4-(thymin-1'-yl)-1,3-dioxolane, all of which are compounds of the formula disclosed in instant claim 1. (column 10, lines 59-64) These compounds are useful in therapeutic methods and pharmaceutical compositions for the treatment and prophylaxis of retroviral infections, particularly HIV. (column 11, lines 33-67, column 12, lines 44-67) The compounds may be formulated and administered in combination with other anti-HIV agents of various types, including the reverse transcriptase inhibitors dideoxycytidine and dideoxyinosine. (column 14, lines 28-63) Thus the claimed invention is anticipated by Belleau et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 13-16, 31-34, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al. (US patent 5852027, cited in PTO-1449) The disclosure of Liotta is discussed above. Liotta et al. does not explicitly disclose a method of treating specifically AZT and 3TC resistant strains of HIV.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods and compositions of Liotta et al. to treat HIV infections resistant to 3TC and AZT. One of ordinary skill in the art would have been motivated to practice the invention in this manner because the invention of Liotta et al. is disclosed to be useful for the treatment and prevention of HIV infections generally. One of ordinary skill in the art would have reasonably expected success because it is well-known, routine and commonplace in the treatment of drug-resistant infections to substitute a different drug to which the infectious agent is not resistant.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 2-4, 13-16, 31-34, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belleau et al. (US patent 7199202, cited in PTO-1449) The disclosure of Belleau et al. is discussed above. Belleau et al. does not explicitly disclose a method of treating specifically AZT and 3TC resistant strains of HIV or the various strains recited in instant claims 45-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods and compositions of Belleau et al. to treat HIV infections resistant to 3TC and AZT and the various strains recited in instant claims 45-47. One of

ordinary skill in the art would have been motivated to practice the invention in this manner because the invention of Belleau et al. is disclosed to be useful for the treatment and prevention of HIV infections generally. One of ordinary skill in the art would have reasonably expected success because it is well-known, routine and commonplace in the treatment of drug-resistant infections to substitute a different drug to which the infectious agent is not resistant.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 5-7, 17, 18, 23-29, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al. (US patent 5852027, cited in PTO-1449) in view of the Merck Manual of Diagnosis and Therapy, seventeenth edition. (Reference included with PTO-892m herein referred to as Merck) The disclosure of Liotta is discussed above. Liotta et al. does not disclose a method or composition additionally comprising a second HIV drug as disclosed in instant claims 5-7, 17, 18, 23-29, 35, and 36.

Merck discloses that patients with HIV be treated with combination therapy of two or more HIV drugs, including two nucleosides. (p. 1321, left column, paragraph 5 – right column paragraph 4) Merck also discloses that 3TC, ddI, ddC, and abacavir are nucleoside anti-HIV drugs, and additionally that NVP and DLV are non-nucleoside anti-HIV drugs. (p. 1322, table 163-3)

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods and compositions of Liotta et al. in combination with an additional anti-HIV drug, particularly a second nucleoside such as 3TC, ddI, ddC, or

abacavir. One of ordinary skill in the art at the time of the invention would have been motivated to combine the references in this manner because Merck discloses that it is standard practice to administer two nucleosides in combination. One of ordinary skill in the art would have reasonably expected success because both the compounds of Liotta et al. and those disclosed by Merck are seen to be useful for the same purpose, that is the treatment of HIV. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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